

## REMARKS

The Office Action mailed on February 11, 2003, has been received and reviewed.

Claims 1-27 are currently pending in the above-referenced application. Each of claims 1-27 stands rejected.

Reconsideration of the above-referenced application is respectfully requested.

### Rejections Under 35 U.S.C. § 102(b)

Claims 1-27 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,004,295 to Langer et al. (hereinafter "Langer").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Langer describes a catheter 28. An operator wire 40 or a conduit catheter 46 extends internally within an injection catheter 58 of the catheter 28, which is, in turn, positioned within a guide catheter 54. Col. 5, lines 23-33; col. 6, lines 23-51; FIGs. 5 and 6. A distal end of the operator wire 40 or conduit catheter 46 is coupled to a plunger 38 which, in turn, is located within and configured to be moved along the length of a cartridge 32 that is located at a distal portion 30 of the guide catheter 54. Col. 5, lines 23-33; FIGs. 5 and 6. The cartridge 32 is also configured to move along the distal portion 30 of the guide catheter 54. Col. 5, lines 13-17; FIGs. 4A-4C. A needle 36 is secured to the outside of the cartridge 32, at an opposite end thereof from the operator wire 40 or conduit catheter 46. Col. 5, lines 23-33; FIGs. 3-4C.

Langer describes two mechanisms for causing the cartridge 32 and plunger 38 to move. Col. 5, lines 34-45; col. 6, lines 53-65; FIGs. 3, 7A, and 7B. A first mechanism, depicted in FIGs. 3 and 7B and described in reference thereto, comprises a syringe 44, which forces hydraulic fluid through the conduit catheter 46 as a plunger of the syringe 44 is forced into a barrel thereof. Col. 5, lines 36-40; col. 6, lines 61-65; FIGs. 3 and 7B. The second mechanism that Langer describes is useful for moving the operator wire 40 through the injection catheter 58,

which is a scissors-type assembly 48, that is depicted in FIGs. 3 and 7A of Langer. Col. 5, lines 40-45; col. 6, lines 55-60. One member of the scissors-type assembly 48 is secured to an end of the operator wire 40, while the other member of the scissors-type assembly 48 is secured to the guide catheter 54. Col. 6, lines 55-60.

As the operator wire 40 is pushed distally through the injection catheter 54 or hydraulic fluid is forced through the conduit catheter 46, the cartridge 32, which is filled with a therapeutic liquid, is forced toward an open, distal end of the catheter 28. Col. 5, lines 45-56; FIGs. 4A-4C. As the cartridge 32 reaches tissue adjacent to which the open, distal end of the catheter 28 has been positioned, the needle 36 is forced into the tissue. *Id.* Further distal movement of the operator wire 40 through the injection catheter 58 or pressure of hydraulic fluid within the conduit catheter 46 causes the plunger 38 to move through the cartridge 32 and, thus, to displace the therapeutic liquid which is contained within the cartridge 32 therefrom, through the needle 36, and into the tissue. *Id.*

It has been asserted by the Office that a catheter, such as that described in Langer, is also a syringe. Office Action of February 11, 2003, page 3. This assertion is purportedly based upon dictionary definitions, as obtained from Webster's, Tenth Edition, for the terms "catheter" and "syringe." It is respectfully submitted that, as will be confirmed by the ensuing description, catheters are not the same as syringes.

In summary, a catheter is itself configured to be introduced into a canal, vessel, passageway, or body cavity of an individual, while a syringe lacks any feature which is configured to be inserted into the body of an individual.

The U.S. Food & Drug Administration (F.D.A.), which implements regulations that govern medical devices, has provided very different definitions for the terms "catheter" and "syringe." For example, 21 C.F.R. § 870.1300 defines a "catheter cannula," which is the body of a catheter, as "a hollow tube which is inserted into a vessel or cavity; this device provides a rigid or semirigid structure which can be connected to a tube or connector" of the catheter.

In contrast, the F.D.A., at 21 C.F.R. §§ 870.5860, has provided the following definition for "syringe": "... a device intended for medical purposes that consists of a calibrated hollow barrel and a moveable plunger. . . At one end of the barrel there is a male connector . . ." It is not the syringe, but an apparatus that is to be connected to the male connector of the syringe that

is configured to be introduced into the body of an individual. By way of example only, the male connector may be coupled with the female end of a hypodermic needle, as indicated by both 21 C.F.R. § 870.5860 and 21 C.F.R. § 5570, which provides:

A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

As another example, a syringe may be “used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.”

21 C.F.R. § 870.1650. When a syringe is used for this purpose, an angiographic catheter, which is separate from the syringe and is configured to be inserted into the heart, great vessels, or coronary arteries, is secured to the male end of the syringe. *See, e.g.*, 21 C.F.R. § 870.1200.

Thus, it is clear that a catheter, such as that described in Langer, is a device which includes a section that is configured to be inserted into the body of an individual, while a syringe, as recited in the claims of the above-referenced application, is a device which remains wholly external to the body of an individual, but which may be coupled to a separate apparatus, such as a hypodermic needle or catheter, which separate apparatus may be inserted into an individual's body.

Due to these recognized differences between catheters and syringes, the industry has separated syringes and catheters into different product categories. This is evident from the product literature and websites of many manufacturers, including, without limitation, AngioDynamics, C.R. Bard, B. Braun, Becton Dickinson ([www.bd.com/products/](http://www.bd.com/products/)), Boston Scientific, Cook, Guidant, Johnson & Johnson (Cordis), Medex Medical, Medtronic, Maxxim Medical, Merit Medical Systems ([www.merit.com](http://www.merit.com)), and St. Jude Medical.

The differences between catheters and syringes having been set forth, reconsideration of the claims is respectfully solicited.

Independent claim 1 of the above-referenced patent application recites a power syringe which includes a syringe barrel that includes a receptacle, a plunger insertable into the receptacle and moveable longitudinally therethrough, and a handle. The handle includes a first member and a second member. The first member of the handle is configured to be held by a first part of a user's hand and is pivotally connected to the syringe barrel. The second member is configured to be held by a second part of a user's hand and is pivotally connected to the plunger. The first and second members are connected to one another in pivotal relation.

It is respectfully submitted that Langer does not anticipate each and every element of independent claim 1 of the above-referenced application for several reasons.

First, as evidenced by the foregoing explanation, it is well known in the art that a catheter, such as that described in Langer, is not a syringe. This is because catheters have a much more limited range of uses than catheters. The uses for catheters are typically limited to the introduction of miniature apparatus into the body of a subject, the delivery of medication or other substances to specific locations within the subject's body, and the obtaining of samples from the subject's body. In each of these cases, the catheter 28 is introduced into the body of the subject. Syringes, in contrast, are not configured to be introduced into the body of a subject. Instead, syringes may be used in conjunction with needles, manifolds, intravenous tubing, IV bags, and a wide variety of different types of catheters, including angioplasty catheters, infusion catheters, and guide catheters. The difference between syringes and catheters is bolstered by the description of Langer, which illustrates and describes use of a syringe, which is separate from the catheter 28 described therein, may be coupled to and used with the catheter 28. *See, e.g.*, FIGs. 3 and 7B. Accordingly, it is respectfully submitted that the catheter described in Langer is not a syringe, as is recited in independent claim 1.

Second, Langer does not expressly or inherently describe a plunger that is insertable into a receptacle of a syringe barrel. Rather, the description of Langer is limited to a plunger 38 that is located within a cartridge 32 positioned within a guide catheter 54. Again, a catheter is not a syringe.

Third, the scissors-type handle 48 described in Langer does not include a member that is "connected to [a] plunger," as recited in independent claim 1. Instead, the scissors-type

handle 48 that is described in Langer includes a member which secured to an operator wire 40, which is, in turn, connected to the plunger 38 thereof.

Fourth, Langer lacks any express or inherent description that a member of the scissors-type handle 48 described therein may be pivotally connected to a plunger of a syringe, as recited in independent claim 1, or, for that matter, that a member of the scissors-type handle 48 may be pivotally connected to the operator wire 40.

In view of the foregoing, it is respectfully submitted that Langer does not anticipate each and every element of independent claim 1 under 35 U.S.C. § 102(b). It is, therefore, respectfully submitted that, under 35 U.S.C. § 102(b), independent claim 1 is allowable over Langer.

Claims 2-10 are each allowable, among other reasons, as depending either directly or indirectly from claim 1, which is allowable.

Claim 2 is further allowable since Langer neither expressly nor inherently describes a power syringe which includes a barrel retaining member for releasably retaining a syringe barrel.

Claim 3 is additionally allowable because Langer does not expressly or inherently describe a power syringe that includes a plunger retaining member for releasably retaining a plunger.

Claim 5 is also allowable since Langer lacks any express or inherent description of a power syringe which includes a handle with at least one of the first and second members thereof comprising a slot through which a hinge extends. Instead, the description of Langer is limited to a mechanical scissors-type handle 48 which merely includes a simple scissors-style hinge with a single, fixed pivot point (*see* FIGs. 3 and 7A).

Claim 6, which depends from claim 5, is further allowable since Langer includes no express or inherent description of a power syringe which includes a handle with at least one of the first and second members comprising an arcuate slot through which a hinge extends. Rather, the description of Langer is limited to a mechanical scissors-type handle 48 which merely includes a simple single, fixed pivot point scissors-type hinge (*see* FIGs. 3 and 7A).

Claim 7, which also depends from claim 5, is additionally allowable because Langer neither expressly nor inherently describes that either the first or second member of the mechanical scissors-type handle 48 described therein includes a slot with teeth that cooperate with teeth of a hinge that pivotally connects the first and second members. Again, the

description of Langer is limited to a mechanical scissors-type handle 48 which merely includes a simple, single, fixed pivot point scissors-type hinge (*see* FIGs. 3 and 7A).

Claim 8 depends from claim 7, and is also allowable since Langer lacks any express or inherent description that teeth of a hinge and teeth of a slot of a handle mutually engage each other to facilitate controlled movement of the hinge along a length of the slot.

Claim 9 is further allowable since Langer does not expressly or inherently describe a power syringe with a handle member that is configured to facilitate gripping thereof. Instead, each of the members of the mechanical scissors-type handle 48 depicted in FIGs. 3 and 7A includes a scissors-type loop, which is configured to receive a finger or thumb, not to be gripped.

Claim 10 is additionally allowable because Langer lacks any express or inherent description that a member of the described mechanical scissors-type handle 48 may be angled. To the contrary, the mechanical scissors-type handles 48 that are depicted in FIGs. 3 and 7A of Langer include straight handle members.

Independent claim 11 recites a handle for a power syringe. The handle includes a first member configured to be secured in pivotal relation to a syringe barrel and a second member configured to be secured in pivotal relation to a syringe plunger. The first and second members of the handle are pivotally secured to one another.

As explained previously herein, the description of Langer is limited to a guide catheter with which either a syringe 44 or a scissors-type handle 48 may be used. Langer does not expressly or inherently describe that a handle with first and second members which are pivotally connected to one another may be used with a syringe.

Moreover, Langer does not expressly or inherently describe that a member of the scissors-type handle 48 thereof is configured to be secured to a syringe barrel. Instead, the description of Langer is limited to coupling of a member of a scissors-type handle to an operator wire 40 of a guide catheter 54 which is, in turn, coupled to a plunger 32.

Further, Langer lacks any express or inherent description that a member of the scissors-type handle thereof is configured to be secured *in pivotal relation to a plunger* of a syringe, let alone to the operator wire 40.

Therefore, it is respectfully submitted that Langer does not anticipate several of the elements that are recited in independent claim 11. Accordingly, it is respectfully submitted that, under 35 U.S.C. § 102(b), independent claim 11 is allowable over Langer.

Each of claims 12-20 is allowable, among other reasons, as depending either directly or indirectly from claim 11, which is allowable.

Claim 13 is additionally allowable since Langer lacks any express or inherent description of a syringe handle with at least one of the first and second members thereof comprising a slot through which a hinge extends. Instead, the description of Langer is limited to a mechanical scissors-style pivoted handle 48' which merely includes a simple scissors-style hinge (*see* FIGs. 3 and 7A).

Claim 14, which depends from claim 13, is further allowable since Langer includes no express or inherent description of a syringe handle with at least one of the first and second members thereof comprising an arcuate slot through which a hinge extends. Rather, the description of Langer is limited to a mechanical scissors-type pivoted handle 48 which merely includes a simple scissors-type hinge with a single, fixed pivot point (*see* FIGs. 3 and 7A).

Claim 15, which also depends from claim 13, is additionally allowable because Langer neither expressly nor inherently describes that either the first or second member of the mechanical scissors-type handle 48 described therein includes a slot with teeth that cooperate with teeth of a hinge that pivotally connects the first and second members. Again, the description of Langer is limited to a mechanical scissors-type handle 48 which merely includes a simple scissors-style hinge with a single, fixed pivot point (*see* FIGs. 3 and 7A).

Claim 16 depends from claim 15, and is also allowable since Langer lacks any express or inherent description that teeth of a hinge and teeth of a slot of a handle mutually engage each other to facilitate controlled movement of the hinge along a length of the slot.

Claim 17 is further allowable since Langer does not expressly or inherently describe that a member of a handle of a power syringe may include a barrel retaining member pivotally secured thereto. Instead, the description of Langer is limited to a mechanical scissors-type handle 48 which includes one jaw that is secured directly to a guide catheter 54.

Claim 18 depends from claim 17 and is also allowable since Langer neither expressly nor inherently describes a power syringe handle which includes a barrel retaining member configured to releasably secure a syringe barrel.

Claim 19 is additionally allowable because Langer includes no express or inherent description of a power syringe handle that includes a member with a plunger retaining member pivotally secured thereto. Rather, the description of Langer is limited to a handle for moving a plunger 38 along a cartridge 32 and a catheter 28, which handle includes a jaw secured to an operator wire 40 that is, in turn, secured to the plunger 38.

Claim 20, which depends from claim 19, is also allowable because Langer does not expressly or inherently describe a plunger retaining member which is configured to releasably secure a syringe plunger.

Turning now to independent claim 21, a method for introducing a fluid into a body is recited. The method of independent claim 21 includes coupling one of an injection apparatus and an infusion apparatus to a syringe barrel in communication with a receptacle of the syringe barrel. In addition, the method of independent claim 21 includes pivoting a first handle associated with the syringe barrel and a second handle associated with a syringe plunger toward one another to force said syringe plunger into a receptacle of the syringe barrel. When such pivoting is effected, the first handle pivots relative to the syringe barrel, the second handle pivots relative to the syringe plunger, and the syringe plunger displaces fluid within the receptacle to force the fluid through the injection apparatus or infusion apparatus and into the body of a subject within which the injection apparatus or infusion apparatus has been placed.

By way of contrast with independent claim 21, the description of Langer is limited to securing *either* a conventional syringe 44 (FIGs. 3 and 7B) *or* a scissors-type handle 48 (FIGs. 3 and 7A) to a guide syringe 54. When the scissors-type handle 48 is used, Langer describes that pivotal movement of the members of the handle 48 forces an operator wire 40 along the guide catheter 54 which, in turn, forces a plunger 38 along the guide catheter.

Langer does not expressly or inherently describe that pivotal movement of the members of the scissors-type handle 48 thereof forces a syringe plunger into a receptacle of a syringe



barrel, as recited in independent claim 21. Instead, the description of Langer is limited to forcing an operator wire 40 through a syringe 28, with the operator wire 40, in turn, forcing a plunger 38 through the syringe 28.

Additionally, Langer lacks any express or inherent description that movement of the scissors-type handle 48 thereof displaces fluid within the receptacle of a syringe barrel, thereby forcing the fluid into and through *another* apparatus, such as an injection apparatus or an infusion apparatus, then into a body. Rather, the description of Langer is limited to movement of the scissors-type handle 48 to force fluid *directly from the catheter 28 (i.e., via the cartridge 32 and needle 36 thereof)* into a body.

Moreover, Langer lacks any express or inherent description that the pivoted handles are associated with a barrel and a plunger of a syringe. Instead, the description of Langer is limited to use of a scissors-type handle 48 with a guide catheter 54, which is clearly not a syringe.

It is, therefore, respectfully submitted that Langer does not anticipate several of the elements that are recited in independent claim 21 and that, under 35 U.S.C. § 102(b), independent claim 21 is, therefore, allowable over Langer.

Claims 22-27 are each allowable, among other reasons, as depending either directly or indirectly from claim 21, which is allowable.

Claim 22 is additionally allowable because the description of Langer is limited to methods for delivering fluids (*see, e.g., col. 1, lines 64-67*), and, thus, for creating positive pressure within a catheter 28. Contrary to the assertion that has been made in the outstanding Office Action that col. 1, lines 22 and 23, and col. 5, lines 40-56, of Langer describe methods for creating negative pressure within a guide catheter, it is respectfully submitted that Langer lacks any express or inherent description of methods for creating a negative pressure within the sampling fluids, as col. 1, lines 22 and 23 describes use of catheters for angioplasty, while col. 5, lines 40-56 describe use of the catheter to insert a needle 36 into a body organ wall.

As such, Langer does not expressly or inherently describe a method for sampling fluids or otherwise drawing fluid into the guide catheter 54 described therein, as is recited in claim 23.

Claim 27 is additionally allowable since Langer neither expressly nor inherently describes introducing an indicator solution into a body.

In view of the foregoing, it is respectfully requested that the 35 U.S.C. § 102(b) rejections of claims 1-27 be withdrawn.

### CONCLUSION

It is respectfully submitted that each of claims 1-27 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing the allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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